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Anders Wieslander

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EXAMINER

DEAK, LESLIE R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,219	Applicant(s) WIESLANDER ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-34 and 38-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-34,38-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/14/06 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 February 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 8, 11, 13, 15-25, 28, 29, 31-34, and 38-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,293,321 to Shinmoto et al in view of US 4,738,668 to Bellotti et al.

In the specification and figures, Shinmoto discloses the apparatus substantially as claimed by applicant.

With regard to claims 1, 8, 28, 29, 31-34, 49, and 50, the overall setup disclosed by Shinmoto comprises a first medical device (patient side) with a patient side first connector 2. The second medical subsystem 4 comprises a bag side connector 5. Each

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subsystem comprises fluid that must be transferred from one subsystem to the other (see FIGS 1A-1C, columns 7-8). The apparatus comprises a closed housing (see column 4, lines 1-4), and allows for the connection and disconnection of the medical fluid subsystems inside the housing (see column 4, lines 18-62). Shinmoto discloses that the apparatus comprises sterilizing means for keeping the interior sterile by providing ultraviolet rays, ozone, heat, or microwaves into the interior of the housing (see column 4, lines 1-4). Since ozone is a gas, it is the position of the Examiner that Shinmoto discloses a gas source of clean gas.

Shinmoto does not disclose that the apparatus comprises a filter and flow generator that push a sterilizing gas to the interior of the connecting apparatus. Bellotti discloses a sterile connection apparatus with an ampoule or disinfectant member 40 in fluid connection with the connector 18. A chemical reaction in the ampoule (or syringe or squeeze bulb) forces a sterilizing gas into the connector 18 through filter 38 creating an overpressure to drive out unsterile gas (see column 6, lines 43-68). Bellotti discloses that the flow generator is capable of being connected and disconnected to the medical device at different points in the procedure, but does not require disconnection. In the syringe embodiment, the plunger of the syringe is configured to deliver at least two separate doses of disinfecting agent by depressing the plunger only a small distance at a time. Accordingly, the Bellotti apparatus is configured to supply gas at all times claimed by Applicant. Bellotti further discloses that the connector may comprise a second aperture, which is capable of holding a second ampoule or syringe of disinfecting agent, allowing the apparatus to supply gas at all times claimed by

Applicant. It has been held that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739 (2007). It is the position of the Examiner that since all the claimed elements are known in the art, it would have been obvious for one of ordinary skill in the art to combine the known elements according to known methods to yield the predictable result of a sterile connection apparatus with a gas flow generator with a filter to sterilize the connector.

With regard to claims 9, 10 14, 39, and 40, Shinmoto discloses that the connection portions comprise cut-off members or caps that must be disconnected prior to fluid connection and reconnected after the connection is complete (see column 4, line 63 to column 5, line 4). As such, the mechanism is capable of performing the function claimed by Applicant.

With regard to claim 11, Shinmoto discloses that the connection apparatus comprises a housing that is opened and closed, indicating that it is capable of giving access to the connection portions when opened (See column 4, lines 18-22).

With regard to claims 13 and 15, Shinmoto discloses that the connection portions are held in holders 20, 21, 22, that move relative to one another to allow the connectors to connect to one another with their shutoff members or caps (see FIGS 1A-1C and accompanying text).

With regard to claims 16-25, applicant claims several functions of the claimed apparatus. Claims 44-48 set forth steps of the method disclosed by Shinmoto. Shinmoto discloses that there are maneuvering means 2 that disconnect the connectors from their

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shutoff members or caps (which may be threaded), and a movable table 23 that moves the connectors along a vertical axis in linear relationship to one another (see column 4, lines 34-62, column 7, lines 45-59). The apparatus further comprises a means to move the connectors horizontally in relationship to one another from a disconnected position to a connected position (see FIGS 1A-1C, column 7, line 24 to column 8, line 8).

With regard to claim 38, Shinmoto discloses that the apparatus comprises sterilizing means for keeping the interior sterile by providing ultraviolet rays, ozone, heat, or microwaves into the interior of the housing (see column 4, lines 1-4).

With regard to claims 41-43, Shinmoto discloses that the apparatus comprises connectors mounted in the receivers in the container. Since such connectors cannot be placed without opening the container, Shinmoto reasonably suggests the steps of opening the container, placing the connectors, and then closing the container before beginning the connection operation disclosed by Shinmoto.

4. In the alternative to the rejection presented above, claims 1, 8, 11, 13, 15-25, 28, 29, 31-34, and 38-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,293,321 to Shinmoto et al in view of US 4,738,668 to Bellotti et al, further in view of US 4,242,310 to Greff et al.

In the specification and figures, Shinmoto discloses the apparatus substantially as claimed by applicant.

With regard to claims 1, 8, 28, 29, 31-34, 49, and 50, the overall setup disclosed by Shinmoto comprises a first medical device (patient side) with a patient side first

connector 2. The second medical subsystem 4 comprises a bag side connector 5. Each subsystem comprises fluid that must be transferred from one subsystem to the other (see FIGS 1A-1C, columns 7-8). The apparatus comprises a closed housing (see column 4, lines 1-4), and allows for the connection and disconnection of the medical fluid subsystems inside the housing (see column 4, lines 18-62). Shinmoto discloses that the apparatus comprises sterilizing means for keeping the interior sterile by providing ultraviolet rays, ozone, heat, or microwaves into the interior of the housing (see column 4, lines 1-4). Since ozone is a gas, it is the position of the Examiner that Shinmoto discloses a gas source of clean gas.

Shinmoto does not disclose that the apparatus comprises a filter and flow generator that push a sterilizing gas to the interior of the connecting apparatus. Bellotti discloses a sterile connection apparatus with an ampoule or disinfectant member 40 in fluid connection with the connector 18. A chemical reaction in the ampoule (or syringe or squeeze bulb) forces a sterilizing gas into the connector 18 through filter 38 creating an overpressure to drive out unsterile gas (see column 6, lines 43-68). Bellotti discloses that the flow generator is capable of being connected and disconnected to the medical device at different points in the procedure, but does not require disconnection. It has been held that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739 (2007). It is the position of the Examiner that since all the claimed elements are known in the art, it would have been obvious for one of ordinary skill in the art to combine the known elements according to

known methods to yield the predictable result of a sterile connection apparatus with a gas flow generator with a filter to sterilize the connector.

Shinmoto and Bellotti do not disclose a selectively activated disinfectant member that is configured to generate disinfectant flow at discrete times. Greff discloses a sterile connection apparatus that comprises an enclosed box with an opening for tubing lines and a selectively activatable can of sterilizing agent, which may comprise ozone (see column 3, lines 50-60). Greff teaches the advantage of a valved sterilizing agent container that allows for selective application of the sterilizing agent to the interior of the connection apparatus. As such, it is the position of the Examiner that it would have been obvious to a person having ordinary skill in the art at the time of the invention to use a valved, selectively activated container of sterilizing agent, as taught by Greff, in the sterile connection apparatus suggested by the cited prior art.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,293,321 to Shinmoto et al in view of US 4,738,668 to Bellotti et al, further in view of US 4,882,496 to Bellotti et al

In the specification and figures, Shinmoto discloses the apparatus substantially as claimed by applicant (see rejection above). With regard to claim 12, the cited prior art does not disclose that the container comprises a base and a cover. However, Bellotti '496 discloses a patient connector apparatus comprising a base 14 that holds connectors, enclosed by lid 12 in order to provide a sterile location for connecting the fluid lines (see FIG2, generally, column 4). Therefore, it would have been obvious at the

time of invention to place the automatic connector apparatus suggested by the cited prior art in an enclosure as disclosed by Bellotti '496 in order to enclose the connectors in a sterile space, as taught by Bellotti '496.

6. In the alternative to the rejection presented above, claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,293,321 to Shinmoto et al in view of US 4,738,668 to Bellotti et al, in view of US 4,242,310 to Greff, further in view of US 4,882,496 to Bellotti et al

In the specification and figures, the cited prior art discloses the apparatus substantially as claimed by applicant (see rejection above). With regard to claim 12, the cited prior art does not disclose that the container comprises a base and a cover. However, Bellotti '496 discloses a patient connector apparatus comprising a base 14 that holds connectors, enclosed by lid 12 in order to provide a sterile location for connecting the fluid lines (see FIG2, generally, column 4). Therefore, it would have been obvious at the time of invention to place the automatic connector apparatus suggested by the cited prior art in an enclosure as disclosed by Bellotti '496 in order to enclose the connectors in a sterile space, as taught by Bellotti '496.

7. Claims 26, 27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,293,321 to Shinmoto et al in view of US 4,738,668 to Bellotti et al, in view of US 4,242,310 to Greff, further in view of US 4,655,573 to Bellotti et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 26, 27, and 30, the cited prior art does not disclose that any of the maneuvering members comprises a user-actuated grip portion. However, Bellotti '573 discloses an aseptic tube connection apparatus that comprises an external handle 64 that is rotated by a user to engage gears inside the closed apparatus to move fluid connections in and out of communication with one another (see column 4, lines 41-50). Since all the elements are known in the art, it would have been obvious for one of ordinary skill in the art to combine the known elements according to known methods to yield the predictable result of a sterile connection apparatus with a manually actuated handle to move the connections into their respective places.

Response to Arguments

8. Applicant's arguments filed 19 February 2009 have been fully considered but they are not persuasive.

9. Applicant argues that Bellotti '668 does not cure the deficiencies of Shinmoto, since it does not disclose a flow generator capable of supplying gas during the connection of the first and second portion and the disconnection of the second portion. Applicant argues that Bellotti discloses a syringe as an alternative to the ampoule disclosed by Bellotti, thereby teaching away from using the syringe in a different manner than that disclosed in the reference. It is the position of the Examiner that the depression of a syringe plunger in either a single, very long stroke (in order to push gas

during both connection and disconnection) or in two discrete strokes does not change the basic principle of operation of the Bellotti apparatus, which merely *prefers* an ampoule in which pressure is generated to force gas into the system.

10. In the alternative to the rationale argued above, the Examiner has presented a separate ground of rejection over the Greff reference.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
16 April 2009